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VI - 510 (K) SUMMARY

Submitted by:

Chelsea Mitchell
Ceremed, Inc.
3643 Lenawee Ave.
Los Angeles, California 90016
Tel: (310) 815-2125
Fax: (310) 815-2130

NOV 2 7 2012

Contact Person:	Chelsea Mitchell
Date Prepared	August 20, 2012
Common/Usual Name:	Soluble Synthetic Polymer Implant Material
Proprietary Name:	Adaptain FastWrap™, Envelock™
Regulation Number:	21 CFR 874.3620
Regulation Name:	Ear, nose and throat synthetic polymer material
Regulatory Class:	II
Product Code:	KHJ
Predicate Device:	Ceremed, Inc. Ceretene™ Soluble Implant Material (K120220)

Description of the device:

Adaptain FastWrap™ is an odorless, opaque wax-like material designed to be utilized directly out of the package. It is best used immediately following removal from the package, and can be softened and increased in stickiness by warming and by additional handling and manipulation, if so desired.

Adaptain FastWrap™ is comprised of a sterile mixture of water-soluble alkylene oxide copolymers (AOC PolymerBlend™). Adaptain FastWrap™ contains no other additives or colorants. Adaptain FastWrap™ is formed in bars and sheets of various sizes with weights ranging from 0.5 to 5 grams each.

Adaptain FastWrap™ is provided sterile by irradiation and must not be resterilized.

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Intended use:
Adaptain FastWrap™ is indicated for use as a water-soluble implant material and as a water-soluble space occupying material as an adjunct during the natural healing process.

Substantial equivalence:
The non-clinical evaluations used to determine substantial equivalence included indications, intended use, design, materials, sterilization, and performance. The comparison demonstrates that the device in this submission is identical in design, materials, indications, performance and sterilization to the predicate Adaptain™ Soluble Implant Material (K120220).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Ceremed, Incorporated
% Ms. Chelsea Mitchell
Vice President, Regulatory Affairs
3643 Lenawee Avenue
Los Angeles, California 90016

November 27, 2012

Re: K122561
Trade/Device Name: Adaptain FastWrap™, Envelock™
Regulation Number: 21 CFR 874.3620
Regulation Name: Ear, nose, and throat synthetic polymer material
Regulatory Class: Class II
Product Code: KHJ
Dated: October 18, 2012
Received: October 19, 2012

Dear Ms. Mitchell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

V. INDICATIONS FOR USE:

510 (k) Number (if known): K122561

Device Name: Adaptain FastWrap™, Envelock™

Indications For Use:
Adaptain FastWrap™ is indicated for use as a water-soluble implant material and as a water-soluble space occupying material as an adjunct during the natural healing process.

Prescription Use_____X_____ (Per 21 CFR 801.109) OR Over-The-Counter Use _____ (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED.)

CONCURRANCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

David Krause

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K122561

Division Sign-Off

510(k) Number_____